

**REMARKS****1. Introduction**

This Amendment is being filed on or before December 13, 2005 in response to the final office mailed on June 13, 2005. Filed simultaneously herewith is a Request for Continued Examination and Petition for a 3-month Extension of Time extending the response date to December 13, 2005, as well as the requisite fees in connection therewith. In light of the foregoing amendment and following remarks, Applicants respectfully request withdrawal of all rejections and a prompt allowance of all pending claims.

All pending claims are cancelled by this amendment. New claims 70-80 have been added. Support for these claims may be found throughout the original specification, and particularly in Examples 1-4.

**2. Relevant Law**

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to a skilled artisan to modify the reference or to combine the reference teachings. M.P.E.P. § 2142. Second, there must be a reasonable expectation of success. *Id.* Finally, the prior art reference or references, when combined, must teach or suggest all the claim limitations. *Id.*; and M.P.E.P. § 2143.03.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure. M.P.E.P. § 2143.01. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination. M.P.E.P. § 2143.01. Moreover, it is improper to base an obviousness rejection on the argument that the claimed combination is "well within the ordinary skill of the art or within the capabilities of a skilled artisan." *Id.* As recently explained in detail by the Federal Circuit:

"As noted above, the suggestion to combine requirement is a safeguard against the use of hindsight combinations to negate patentability. While the skill level is a component of the inquiry for a suggestion to combine, a lofty level of skill alone does not suffice to supply a motivation to combine. Otherwise a high level of ordinary skill in an art field would almost always preclude patentable inventions.

As this court has often noted, invention itself is the process of combining prior art in a nonobvious manner. *See, e.g.,* Richdel, 714 F.2d at 1579; Environmental Designs, 713 F.2d at 698. Therefore, even when the level of skill in the art is high, the Board ***must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination.*** *Cf. Gechter v. Davidson*, 116 F.3d 1454, 43 USPQ2d 1030 (Fed. Cir. 1997) (explaining that the Board's opinion must describe the basis for its decision). In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."

*In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998).

And while it is recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, reliance on knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. *See In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Drawing on hindsight knowledge of the claimed invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction - an illogical and inappropriate process by which to determine patentability. *Sensonics, Inc. v. Aerosonic, Corp.*, 38 USPQ2d 1551 (Fed. Cir. 1996). Thus, where there is no motivation to modify a reference, the rejection has been based on impermissible hindsight and the rejection is improper.

Moreover, "***determination of obviousness can not be based on a combination of components selectively culled from the prior art to fit the parameters of the claimed invention.***" *ATD Corp. v. Lydall, Inc.*, 48 USPQ2d 1321 (Fed. Cir. 1998).

### 3. Rejection of Claims 1, 3-5, and 62-67 Under 35 U.S.C. § 103

In the rejection mailed on June 13, 2005, the Examiner asserts that: (1) olestra as a non *in vivo* hydrolyzable ester would be an exception to the general rule; (2) applicants have not shown that an ester of polycosanols with PUFA are not cleaved *in vivo*; and (3) "Examples 1-5 provide no clear and convincing evidence of non obviousness or unexpected results over the cited prior art since there is no side by side comparison with the closest prior art."

The Examiner's current argument that "the polycosanols esters of the fatty acids claimed herein is **not** the sucrose esters of fatty acids also known as Olestra, nor is structurally similar to Olestra" appears to be in contradiction to the basis of the rejection mailed on June 18, 2003 in which the Examiner asserted, as an established truth, quoting Bungaard, that **all** esters of actives are hydrolyzed *in vivo*: "*esters of actives containing hydroxyl and carboxyl groups (also known*

*as hydroxyl group and carboxyl group in carboxylic acid conjugated or esterified by an ester bond) are hydrolyzed within the body (in vivo) by cleaving the ester bond to regenerate the active drug substances.” See Office Action mailed June 18, 2003, page 7.*

Thereafter, applicants pointed out that the above statement was not a truism and produced a specific and well known example of a non-hydrolyzable synthetic ester. In the current rejection, the Examiner responds that “the polycosanols of the fatty acids claimed herein is **not** the sucrose ester of fatty acids also known as Olestra, nor is structurally similar to Olestra”. In so stating, the Examiner appears to rely upon a theory or theoretical model which predicts which esters are cleavable and which esters are not cleavable. The Examiner provides no citation for such theory or model but rather appears to rely upon the Examiner’s own knowledge. Therefore, applicants respectfully request the Examiner provide an affidavit under 37 CFR 104(d)(2) which states:

Insert B.

Although applicants have provided a concrete example of an ester of an active nonhydrolyzable *in vivo*, the Examiner yet states that applicants fail “to set forth evidence substantiating this belief that the claimed polycosanol ester of the fatty acids would not be hydrolyzed within the body (*in vivo*) by cleaving the ester bond to regenerate two active drugs, the polycosanol and linoleic acid, or EPA or DHA in the body.” Office Action mailed on June 13, 2005, page 7 (emphasis in original). Again, the Examiner appears to rely upon personal information that Olestra is somehow unique and that no other synthetic esters would behave in the manner of Olestra. Like Olestra, polycosanol esters with PUFA are not found in nature and are not found in any natural food source. **Therefore the ability of pancreatic esterase to act on polycosanol esters with PUFA, is not prima facie obvious.**

The Examiner further fails to recognize the fact that Olestra, despite not being hydrolyzed within the body, exerts a notable cholesterol lowering effect. See Patterson et al., “Changes in Diet, Weight, and Serum Lipid Levels Associated With Olestra Consumption” *Arch. Intern. Med.* 2000; 160:2593-2599. Therefore, *in vivo* hydrolysis is not a *sine qua non* for having physiological effect.

Yet another “exception” contrary to Bungard’s assertion is exhibited by beta-sitosterol and beta-sitosterol esters of fatty acids. Food composition containing beta-sitosterol for lowering cholesterol are disclosed in US Patent 5,932,562. US Patent 5,958,913 discloses food compositions for lowering cholesterol, containing *esters* of beta-sitosterol with common food

fatty acids. But, surprisingly, said esters exhibited a significantly higher cholesterol lowering effect than beta-sitosterol alone. Based upon the Examiner's theories, the Examiner would have expected the cleaving of the ester bond to regenerate the active beta-sitosterol. None of the fatty acids of rape seed oil are known for their cholesterol lowering effect. As with the polycosanols, the sitosterol esters of the fatty acids "claimed herein is **not** the sucrose esters of fatty acids also known as Olestra, nor is structurally similar". Quoting Office Action mailed on June 13, 2005, page 7. Whether sitosterol esters are hydrolyzed within the body or not, their unexpected effect with respect to free stanols arose from being administered in the form of an ester. Thus, the applicants have provided two examples of fatty acid esters of widely different chemical nature, whose cholesterol lowering effect do not fit in the "theory" of Bungaard as espoused by the Examiner.

Therefore, the Examiner's view that one of ordinary skill in the art would consider that all esters are hydrolyzed within the body and that their effects are due to the hydrolyzed moieties and would be merely additive is factually incorrect.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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